IMPACT OF 'ADL SELF-MANAGEMENT MODULE' ON HEALTH RELATED QUALITY OF LIFE AMONG ROAD TRAFFIC ACCIDENTS' PATIENTS: A QUASI-EXPERIMENTAL RESEARCH APPROACH

Majed E. Al Thomali [1], Muhamad Hanafiah Juni [2*], Rosliza Abdul Manaf [2], Hayati Kadir Shahar [2] and **Abdelsafi Abbas Mohammed Gabbad [3]**

[1] Ph.D., Candidate, Department of Community Health, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 UPM Serdang, Selangor Darul Ehsan, Malaysia.

[2] Department of Community Health, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, 43400 UPM Serdang, Selangor Darul Ehsan, Malaysia.

[3] Department of Epidemiology, College of Health Sciences, Umm Alqura University, Al-Lieth, Makkah, Saudi Arabia.

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ABSTRACT

Background: Road traffic accidents represent a community and governmental concern in Saudi Arabia and worldwide. In addition, road traffic accidents injuries are among the main causes of physical impairment and functional dependency. Therefore, performance of activity of daily living of those injured patients are severely affected due to loss of independence. Subsequently, quality of life is affected as well. **Objective:** To develop, implement and evaluate the impact of "ADL self-management module" on health related quality of life among road traffic accidents' patients. **Methods/design:** A quasi experimental study design will be conducted in Saudi Arabia in which 152 orthopedic patients with lower extremities fractures due to road traffic accidents who have difficulty in carrying out daily activity will be recruited from the study hospitals based on Barthel Index. The patients in the intervention group will provided with the ADL Self-Management Module in a form of an educational material. They will be supplemented in that module with knowledge, skills and confidence to engage in self-management of activity of daily living tasks independently, whereas the control group will receive the usual care. Descriptive analysis, chi square and Generalized Estimation Equation, Independent t test will be used to test the differences of activity of daily living and health related quality of life between and within the groups. **Discussion:** To our knowledge, this is the first experimental study that will conducted in Saudi Arabia on ADL self-management to improve the quality of life of Road Traffic Accident survivors who have difficulty in performing daily activities.

1. INTRODUCTION

Road traffic accidents (RTAs) represent a community and governmental concern in Saudi Arabia and worldwide. Many countries over the world especially the developing confront high incidence of RTAs, which lead consequently to injuries, disabilities and deaths (Al Turki, 2013). Global status report on road safety by World Health Organization, (WHO) in (2013) states that, RTAs injure tens of millions and kill 1.24 million people every year worldwide; 90% of them in the developing countries and 60% of deaths are among the age of young adult from15 to 44 years old. In addition, more than one third of RTAs global deaths occurred in low and middle income countries. The African countries followed by middle terrain represent the highest global incidence of road traffic deaths (WHO, 2013).

There are a lot of studies that focus on the number of deaths and injuries caused by RTAs and other type of trauma. However, the outcomes of RTAs are beyond the number of survived people. It is more on to which extend Health Related Quality of Life (HRQOL) is being affected (Alghnam, Alkelya, Al-Bedah, & Al-Enazi, 2014; Holtslag et al., 2008).

HRQOL regarded as one of the long term health outcomes indicators for people with RTAs injuries. A big portion of RTAs victims suffer different type of physical, psychological, social and functional injuries and disability which as a result affect their HRQOL negatively (Hassan, 2010; Pashaei Sabet et al., 2016). RTAs survivors who have functional disability due to physical and psychological injuries are vulnerable to have poor HRQOL (Undavalli, Das, Dutt, Bhoi, & Kashyap, 2014). Moreover, HRQOL can be best anticipated by functional activity performance of patients with fractures caused by RTAs or other type trauma injuries (Zhang et al., 2012).

RTAs injuries have profound effect on activity of daily living due to restricted physical tasks and roles that lead to poor HRQOL (Barnes & Thomas, 2006). Therefore, interventions that focus on ADL rehabilitation would improve HRQOL of those injured individuals. In the same context, improvement of functional activities through Activity of Daily Living (ADL) education could improve HRQOL as well (Haghgoo, Pazuki, Hosseini, & Rassafiani, 2013).

Rehabilitations services play an essential role to involve and empower patients with injuries who have difficulty in ADL performance in care process. Participation of patients in management of self-care enables independency and improves health status outcomes (Ryan & Sawin, 2009). In addition rehabilitation interventions that focus on self- management and self-care are good choice to promote HRQOL (Tung et al., 2013). RTAs survivors with functional disabilities need to learn new strategy of self-management in order to return to normal life and re-assume their social and family roles. They lack of knowledge and skills needed to reduce dependency and empower them to reach the stage of ability to self-manage their health condition (Pashaei Sabet et al., 2016).

The aim of this study is to develop, implement and evaluate the impact of "ADL self-management module" on activity of daily living status and health related quality of life among road traffic accidents' patients in Taif City, Saudi Arabia.

2. THEORETICAL APPROACH

The theoretical approach of this study is built on Self- management (SM) concept that was originated based on the self-efficacy theory which refer to the patient's belief in his

or her own ability to manage illnesses by acquiring needed skills and knowledge. SM aims to empower patients to be able to control over their current health restriction to improve quality of life and health outcomes (Johnston, Liddy, Ives, & Soto, 2008). In other words, when individuals participate in management of their self-care, they will show better-quality health outcomes (Ryan & Sawin, 2009).

SM encompasses in its implicit emphasis on patient empowerment. Furthermore, patient empowerment refers to patients awareness of their role through knowledge and skills provided to them to perform task and participate in the care process with respect of culture and patients differences (WHO, 2009). Patient empowerment is a new and essential approach that encourage the patients to be in control of their daily care and to have an independency for needed behavior changes, hence, they should be granted with chances to have the knowledge and skills within appropriate environment to shift the care strategy toward active participation instead of care recipient (Anderson & Funnell, 2010). Moreover, empowerment is the development of educational approach to promote patients' skills, knowledge and attitude to be in charge of their health choices (Feste & Anderson, 1995). SM relies on five elements, namely patient' readiness or motivation, information/knowledge, skills, environment resources and social support (Rotheram-Borus, Ingram, Swendeman, & Lee, 2012).

With reference to what has been discussed above, Individuals and Family Self-Management Theory (IFSMT) is selected as a theoretical framework to guide throughout the whole process of this study. IFSMT has been selected because of its appropriateness and suitability for the current research. It offers evidence based guidance and direction on how to employ SM effectively to improve and predict SM behavior and HRQOL for individuals with health problems. It also clearly, identified SM contextual and process factors that need to be taken into account when developing intervention program aiming to activate engagement in SM and improve health status and HRQOL.

Figure – 1: *Individuals and Family Self-Management Theory (IFSMT)*
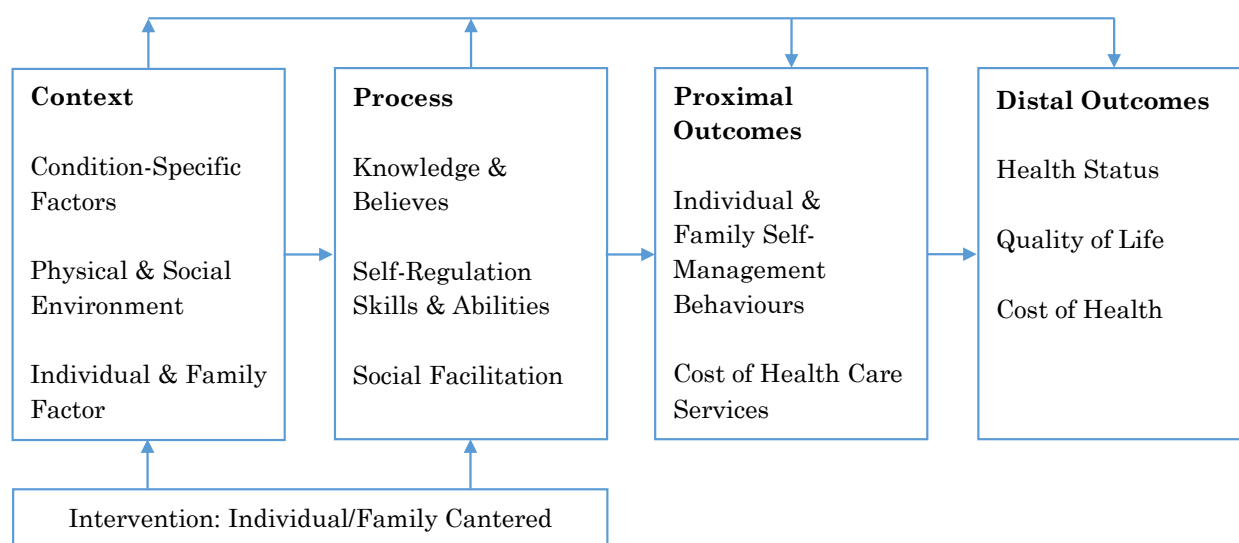

Source: Ryan and Sawin 2009, 2014

IFSMT was developed by Ryan and Sawin that combined individual and family SM and linked their related concepts (Craft-Rosenberg & Pehler, 2011). IFSMT consists of four

concepts as illustrated in figure 1 which are context, process, proximal and distal outcomes. Each concept of IFSMT has different domains. For instance, concept of context encompasses condition specific factors, physical and social environment and individual and family factors. While concept of process includes knowledge and beliefs, self-regulation and ability and social facilitation. Proximal outcomes are reflected through the individual and family self-management behavior, and cost of health care services domains. Finally, distal outcomes involve health status, quality of life and cost of health. The health services cost and cost of health will not be studied because it not among of the scope of this research.

3. CONCEPTUAL FRAMEWORK

The conceptual framework of this research as shown in Figure 2 demonstrates the inter-relation between the study variables where the RTAs orthopedic injuries affect the injured survivors' ADL and HRQOL. The intensity and magnitude of this effect are vary based on many contextual factors. The contextual factors are age, gender, educational level, marital and employment status, associated injury, numbers and location of fractures. In the process where the ADL self-management intervention will be introduced, the participants' level of knowledge, believes, skills and confidence influence the health outcomes. ADL self-management intervention aims to empower patients and increase the level activation to participate in self-care process through the provision of knowledge, skills, believes and confidence to influence positively the self-management of ADL and HRQOL.

Figure – 2: *Conceptual Framework*
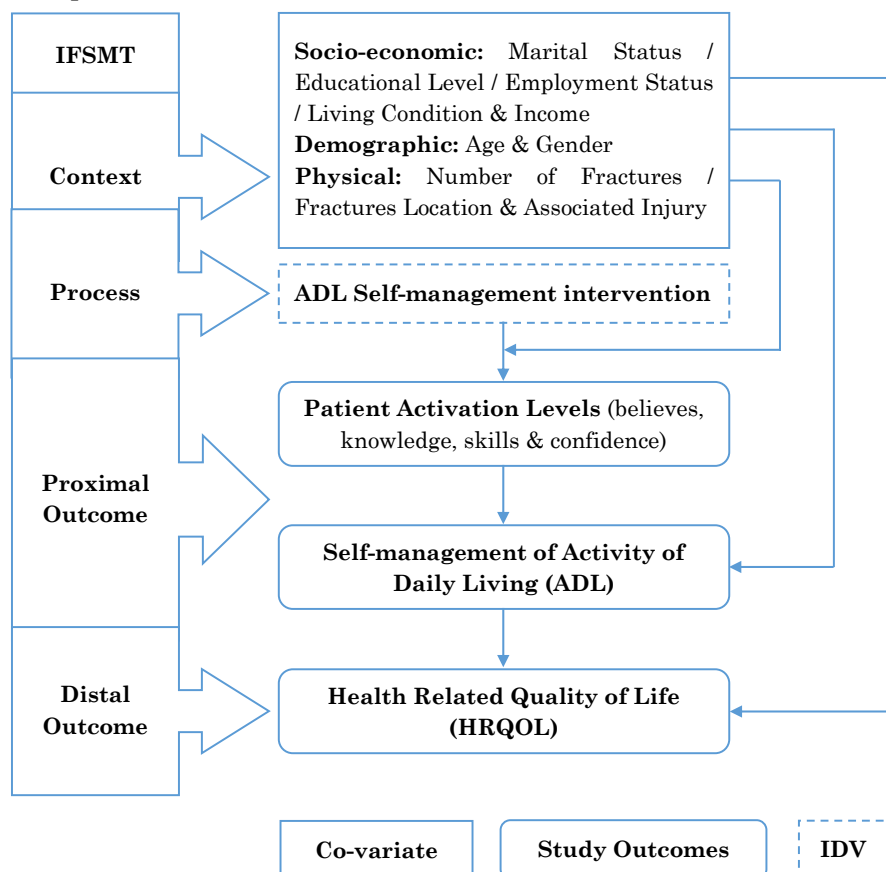
Based on IFSMT, RTAs injured patients have to believe that they are able to manage their health problem by acquiring new skills and knowledge on how to stay independently in carrying out their own daily routine activities. Thus, they will be supplemented with educational materials that contain steps of instruction and information to gain the skills, knowledge and confidence. Therefore, improve their ADL and HRQOL.

4. METHOD

4.1 Study Design

The study design is a pre-post time series quasi-experimental design with control group. This design is selected because of difficulty in performing randomization at group level due to the availability of only two hospitals. It is also not possible to do randomization at individual level to avoid contamination. It is selected as intervention study based on previous recommendation that an ADL intervention could improve HRQOL (Haghgoo et al., 2013). The study will be conducted in Saudi Arabia. There are only two hospitals eligible to the study in which they will be assigned as an intervention and control hospital. They are the largest two referral hospitals and all RTAs injured patients are usually referred to them from periphery or private hospitals for admission and treatment. They are quite similar in bed capacity, health services provided, specialities and manpower. The participants will be recruited from study hospitals who are eligible for the study based on inclusion and exclusion criteria.
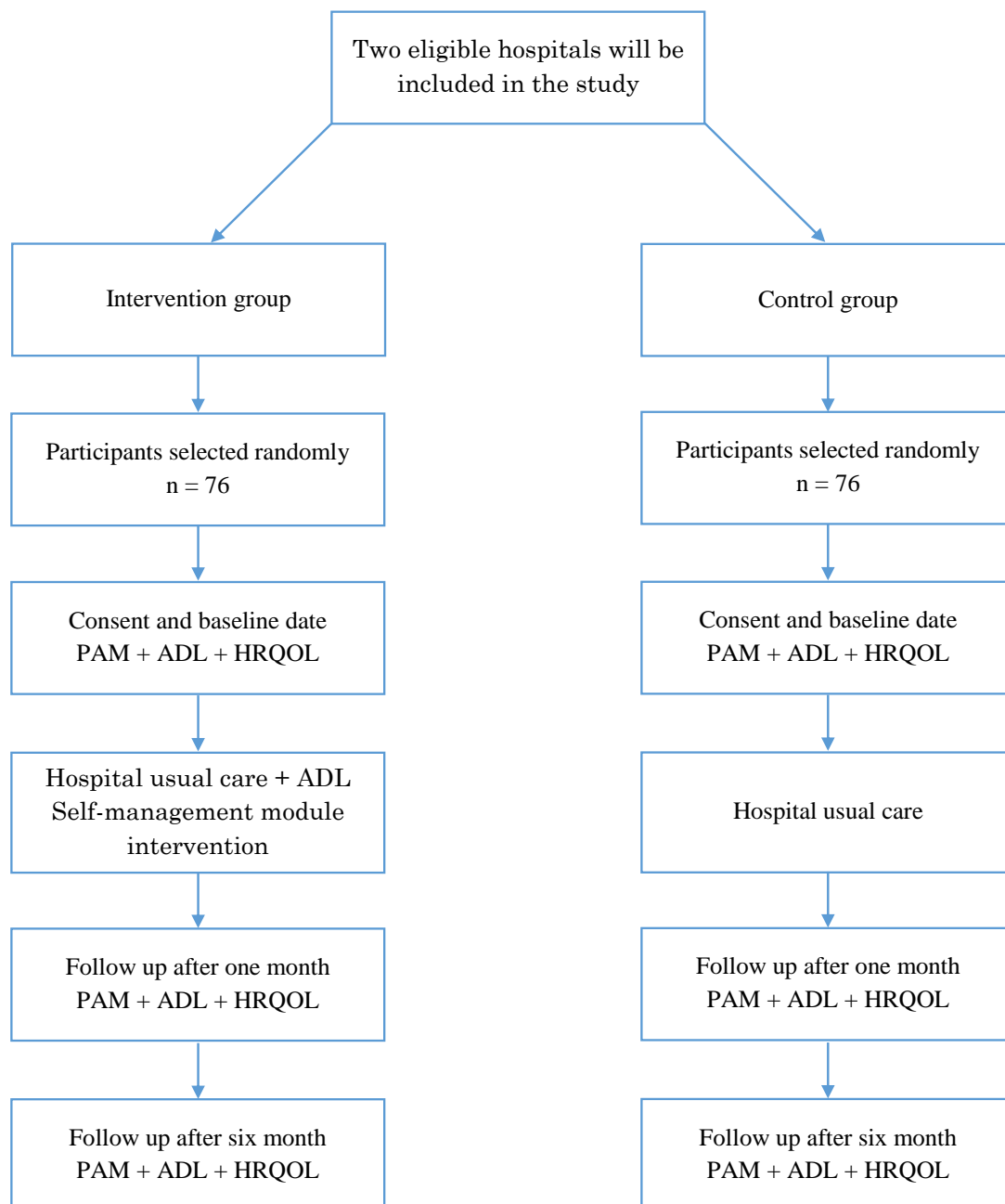
4.2 Study Flow

AS shown in Figure 3, the participants in the intervention and control group will be selected randomly using stratification random sampling, then simple random sampling will be used to select the participants from each stratum. The included participants will be asked voluntarily to sign an informed consent. Later, baseline data will be obtained for both groups including socio-demographic data such as age, gender, educational level, marital status, home condition, employment status, income, associated injury, number and location of fracture. In addition, patient activation for self-management, ADL and HRQOL will be measured using patient activation measure (PAM), modified Barthel Index (BI) and EQ5D instruments. The control group will receive the hospital usual care, while the intervention group in addition to the usual hospital care will be provided with "ADL self-management module" which is an educational material designed based on individual and family self-management theory (IFSMT) to empower patients to self-manage their ADL independently. One and six months after the intervention, both groups will be followed up for patient activation toward self-management, ADL status and HRQOL. The study will take place for a period of twelve months including the pilot and main study.

4.3 Inclusion and Exclusion Criteria

The study includes all new patients admitted from emergency unit to orthopedic units for treatment of RTAs injury who have lower extremities fractures, and have ADL score of 15 to 80 based on Barthel Index (BI) assessment tool. It also includes those patients who are Saudi between 18 to 59 years old, and fully conscious and oriented. The illiterate

patients and who are referred to orthopedic unit for admission from ICU or high dependency unit or other units and those patients with pre-injury chronic condition will be excluded.

Figure – 3: *Study Flow Chart*

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                    ┌─────────────────────────────┐
                    │ Two eligible hospitals will  │
                    │    be included in the study  │
                    └─────────────────────────────┘
                      /                          \
    ┌──────────────────────┐          ┌──────────────────────┐
    │  Intervention group   │          │     Control group    │
    └──────────────────────┘          └──────────────────────┘
              │                                   │
    ┌──────────────────────┐          ┌──────────────────────┐
    │ Participants selected │          │ Participants selected │
    │  randomly   n = 76    │          │  randomly   n = 76    │
    └──────────────────────┘          └──────────────────────┘
              │                                   │
    ┌──────────────────────┐          ┌──────────────────────┐
    │ Consent and baseline  │          │ Consent and baseline  │
    │  date PAM + ADL +     │          │  date PAM + ADL +     │
    │        HRQOL          │          │        HRQOL          │
    └──────────────────────┘          └──────────────────────┘
              │                                   │
    ┌──────────────────────┐          ┌──────────────────────┐
    │ Hospital usual care + │          │                       │
    │ ADL Self-management   │          │  Hospital usual care  │
    │  module intervention  │          │                       │
    └──────────────────────┘          └──────────────────────┘
              │                                   │
    ┌──────────────────────┐          ┌──────────────────────┐
    │ Follow up after one   │          │ Follow up after one   │
    │   month PAM + ADL +   │          │   month PAM + ADL +   │
    │        HRQOL          │          │        HRQOL          │
    └──────────────────────┘          └──────────────────────┘
              │                                   │
    ┌──────────────────────┐          ┌──────────────────────┐
    │ Follow up after six   │          │ Follow up after six   │
    │   month PAM + ADL +   │          │   month PAM + ADL +   │
    │        HRQOL          │          │        HRQOL          │
    └──────────────────────┘          └──────────────────────┘
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4.4. Sampling Methods

Eighty-five percent of RTAs patients admitted to orthopedic are male and the other 15% are female. To obtain representative sample, stratified sampling technique will be used to generate 65 male patients and 11 females out of 76 patients required for each group. The patients from each stratum will be selected randomly using simple random sampling technique as illustrated below in figure 4.

Figure – 4: *Sampling methods flow for each group*

| New patients admitted to orthopaedic units |
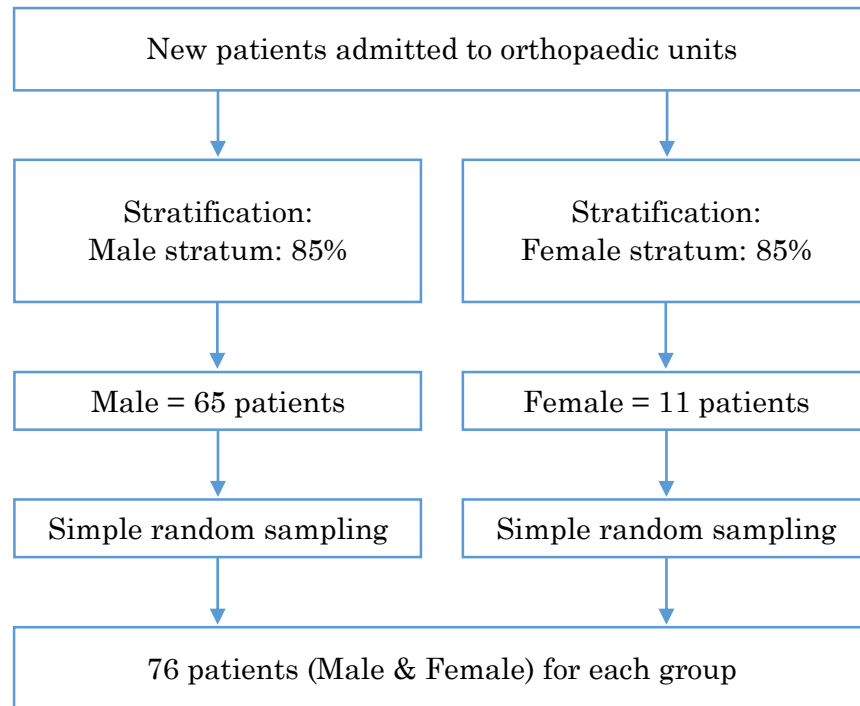
4.5 Matching

Each participant in intervention group will be matched from control group. The matching will be based on the variables, age, gender, associated injury and number of fracture.

4.6 Sample Size

The sample size will be calculated based on hypothesis testing of two population means formula by Lemeshow, Hosmer, Klar, Lwanga, & WHO (1990). The sample size for HRQOL according to the study of Franzén, Brulin, Stenlund, & Björnstig (2009) is:

$$\sigma\,pooled = \sqrt{\frac{\sigma 1^2 + \sigma 2^2}{2}} = 15.5$$

$$n = \frac{2\sigma^2[\,Z_{1-\alpha/2}+Z_{1-\beta}]^2}{(\mu1-\mu2)^2} \qquad n = \frac{2*15.5^2[\,1.96+1.28]^2}{(65.4-84.8)^2} \qquad n = \frac{5044}{376} = 13$$

The sample size for ADL according to Studenski et al., (2005) is:

$$\sigma\,pooled = \sqrt{\frac{\sigma 1^2 + \sigma 2^2}{2}} = 2.9$$

$$n = \frac{2\sigma^2[\,Z_{1-\alpha/2}+Z_{1-\beta}]^2}{(\mu1-\mu2)^2} \qquad n = \frac{2*2.9^2[\,1.96+1.28]^2}{(92.6-94.3)^2} \qquad n = \frac{176}{2.9} = 61$$

n: sample size   σ: pooled standard deviation = 2.9   µ1-µ2=2.9

Two tailed   Z1-α/2 = 1.96   power 90%   Z1-ß= 1.28

n = 61 + 20% (attrition rate) = 76 patients for each arm

As shown above, sample size was calculated for both outcomes, ADL and HRQOL. The largest sample size were selected which was ADL. The level of significant will be set at 5% (α=0.05) with CI 95%. The desired power is 90% (ß=1.28) of detecting an increase of 2.9 in ADL score using two-tailed test. The σ is 2.9 based on previous study of Studenski et al., (2005).The sample size obtained is 61 patients required for each arm. In order to consider for attrition rate of 20%, the following formula is used: N (number to enroll) = desired sample size/ (% retained) 122/.80 = 152/2 = 76 patients needed for each group.

4.6 Instruments
4.6.1 Patient's Characteristics and Socio-Demographic Questionnaire

This questionnaire obtains information about demographic, socio-economic, and injury characteristics.

4.6.2 Patient Activation Measure (PAM)

PAM has been developed by Judith H Hibbard and colleagues in 2004 at Oregon University. It measures patients' believes, knowledge, skills and confidence to self-manage their health problems (Hibbard, Mahoney, Stockard, & Tusler, 2005). This instrument aimed to help in controlling cost, improve health quality of care through activation of patients' participation in their care process (Hibbard, Stockard, Mahoney, & Tusler, 2004). PAM consists of 13 items that provides a total score ranges between 0-100 classified on four activation levels. It helps to assess patient's activation in engagement to manage one's health condition. Individuals who have high activation score are more likely skillful, knowledgeable and highly motivated to take a role in managing their own health problems. Therefore, they improved their health outcomes (Insignia Health, 2017).

4.6.3 Barthel Index (BI)

Barthel Index (BI) is a tool that will be used to assess the functional level of dependency of individuals in 10 areas of daily self-activity which include, bowel and bladder control, toilet use, movement, grooming, dressing, feeding, mobility, transfer, and stair climbing (Sackley et al., 2015). Each area score ranks from 0, 5, or 10 to 15. BI was created initially to assess stroke patient's degree of disability. Later, it became used popularly for many health condition such as, neuromuscular and musculoskeletal diseases (Marvin & Zeltzer, 2017). The BI has been modified based on the condition of this research participants. Therefore, the domains of feeding and grooming have removed due to inappropriateness to lower extremities fractures who are independent for feeding and grooming. The total score of BI after modification will be changed from 100 to 85. The lowest score indicate dependency on self-care and disability. The highest score, the better independency. BI will be administered by researcher team member through patient interview. This instrument was used in Saudi Arabia in medical field research in the study of Sami, Shirley & Nadina (2015) titled as Prevalence of Post-stroke Emotional Disorders in Saudi Arabia.

4.6.4 European Quality of Life (EQ5D) 3 Levels

EQ5D 3L is a self-administered tool in a form of questionnaire to evaluate the HRQOL. It is consisted of five areas (mobility, self-care, usual activities, pain ⁄ discomfort and anxiety ⁄ depression), each area is scored from 1 (I have no problem), 2 (I have some problem) to 3 (I have extreme problem). It has two parts, the first part contains descriptive ordinal scores, whilst, the second part is a single measurement score ranged between 0 to100. The lower score reflects poor HRQOL, whereas, the high score indicates better HRQOL. This tool is commonly used in literatures and was used in Saudi Arabia with diabetic patients in the study of Al-Aboudi et al. (2015) titled: "health related quality of life among type 2 diabetic patients in Riyadh". It is a popular instrument being used in different research and study due to its generalizability and comparability particularly in studies that measure HRQOL and daily life welfare (Brooks, 1996). This instrument will be used together with PAM and modified BI in all the stages of the research data collection which are pre intervention, one and six months' post intervention.

4.7 Validity and Reliability of Study Instruments

To ensure validity and reliability of PAM, modified BI and EQ5D 3L prior to use in the main study, they will be tested for construct validity and Cronbach's alpha for internal consistency reliability on similar group of participants other than those in the main study.

4.8 Intervention

ADL Self-Management Module is an educational material that will be developed by the researcher and written in Arabic language based on Individuals and Family Self-Management Theory (IFSMT) as an intervention module as illustrated in Table1. It targets orthopedic patients with lower extremities fractures that caused by RTAs. The material is divided into five sections. The first section is instructions on how to use the material. In the second section, the material provides general information on RTAs injuries and their role in functional disability and difficulty in performing ADL. While the third section was about self-management and its importance in patient empowerment to carry out ADL independently which as result could improve one's well-being and quality of life. The fourth section contains information and statement specified to pose beliefs, and influence motivation to engage in the participation of self-management and control over health problem resulted from RTA injury were provided. Finally, the fifth section is aimed to improve the patient's skills to self- manage their own daily activities. This section is arranged by each basic ADL functions or area namely, bathing, dressing, bowel and bladder control, transfer, mobility and stairs climbing. In each area, there will be instructions and steps along with pictures for illustration on how to carry out each single task of ADL in an alternative and safe way. Only those patients who are eligible to for research inclusion based on BI screening will be given the material. It will be given to the patients after obtaining the baseline data which include socio-demographic, patients' characteristics, patient's activation, ADL and HRQOL measurement. The patients will be provided with enough time to read and absorb the information and then will be allowed to ask question and seek clarification for any query or unclear items in the material. Each patient also will be asked and reminded regularly to read the material and try to follow and apply the instructions written when going to carry out every single activity.

Table – 1: *Summary of ADL Self-management Module Components Development Based on Individuals and Family Self-Management Theory (IFSMT)*

	IFSMT	**Content**	**Measurement**
1	**Context**		Questionnaire: Socio-economic, demographic and patients' characteristics data questionnaire
2	**Process: Knowledge, skills, confidence and believes**	ADL self-management intervention: Is an educational material that was arranged into five sections: I. General instructions on how to use the educational material II. Knowledge and information on: 1. RTAs and lower extremities fractures 2. ADL 3. Consequences of lower extremities fractures on performance of ADL III Self-management IV. Beliefs and motivation V. Skills to self-manage ADL: It consists of written instructions along with pictures to guide patients with lower extremities fractures on how to perform ADL independently.	
3	**Proximal outcome:** 1. Patient activation level 2. Self-management of ADL		1. Patient Activation Measure (PAM): assess patients believes, knowledge, skills and confidence for self-management Questionnaire 2. Barthel Index (BI)
4	**Distal outcome:** HRQOL		Questionnaire: EQ5D

4.8.1 Validity and Reliability of ADL Self-management Module

Prior to its use in the main study, the material will be tested for face and content validity. It will be reviewed by a panel of experts for its information relevance, clarity and

language understanding. Feedback from the patients regarding the material and its contents will be obtained. After material is face and content validated, a Pre- post pilot study will be conducted on orthopedic patients with fractures due to RTAs other than those in the main study. Once the educational material is validated, it will be used in the main study as ADL Self-Management Module.

4.9 Study Primary Outcomes
4.9.1 Health Related Quality of Life (HRQOL)

HRQOL is defined for the purpose of this research as the personal displayed or expressed perception of own health status provided by individuals in response to lower extremities fractures due to RTAs injury across EQ5D3L for HRQOL scale components such as mobility, self-care, usual activity, pain/discomfort and depression/anxiety in a form of quantifiable measurement scores. HRQOL will be measured using EQ5D instrument before intervention, after one month and at six months of intervention.

4.10 Study Secondary Outcomes
4.10.1 Activity of Daily Living (ADL)

ADL can define as the basic and routine self-care activities essential for daily life that can be performed by orthopedic patients such as, personal hygiene, grooming, dressing, bowel and bladder control, movement and transfer. ADL will be assessed using modified Barthel Index (BI) initially as screening to recruit the patients and baseline data, after one month of the intervention and finally after six months.

4.10.2 Patient Activation

Patient activation level is the degree of RTAs injured patient engagement to participate actively in the care process and self-manage their daily activities independently based on the level of knowledge, skills, beliefs and confidence they possessed. Patient activation level will be measured using PAM at three times, pre, one month and at six months' post ADL self-management intervention.

4.11 Statistical Analysis

The date will be analyzed using SPSS software program version 22. Socio-demographic and patients' characteristics data will be analyzed descriptively using central tendency, dispersion and chi square. Generalized Estimating Equation (GEE) will be used to determine the differences in the mean of ADL status and HRQOL within groups. In addition, independent t test will be used to determine the differences in the mean of ADL status and HRQOL between groups. For the predictors of ADL and HEQOL, Multiple Linear Regression (MLR) will utilized.

5. RESULTS

At baseline, it is expected that there will be no significant differences in patients' socio-demographic, characteristics and study outcomes. After introduction of "ADL self-management module" intervention, both groups are expected to improve in patient activation, ADL and EQ5D. However, the improvement will be more in intervention group

compared to control group. Therefore, there will be significant differences between and within the groups.

6. DISCUSSION

This research is about RTAs injured patients who represent significant number in Saudi Arabia. In addition, to our knowledge, there was no study has examined patient activation for ADL self-management and HRQOL among those group of patients previously in Saudi Arabia. Therefore, this research would add to the existing body of knowledge in the field by assessing patient activation for ADL self-management and HRQOL and try to introduce an intervention program to improve HRQOL through optimizing ADL self-management of RTAs injured patients. This research also, may provide beneficial values to health system by improving quality of care of RTAs injured patients, increasing the efficiency of health services through an ADL self-management module that encourage patients' involvement in recovery and rehabilitation process and empower them to control over their health problems. Similarly, it may also shorten recovery and rehabilitation period, hence, reduce hospital stay which as a result could lead to lessen the financial burden.

This research will be conducted in one City only, thus, the results generalization is limited to this particular City. It is, difficult to extend this research to more than one City due to financial barriers and long distances between Cities in Saudi Arabia. In addition, there will be limitations in term of research design such as lacking of randomization. Therefore, in quasi experimental design, the internal validity to make inference of causality might be difficult due to lacking of participants' randomization to intervention or control group.

When ADL Self-management intervention is adapted as a protocol for the rehabilitation of RTAs injured patients or other type of patients, this would help the patients to gain privileges to improve their ability to carry out ADL independently. Likewise, improve their physical and mental condition which lead finally to improve HRQOL.

7. CONCLUSION

This study is pertaining RTAs injured patients who represent significant number in Saudi Arabia. In addition, there was no study have examined patient activation for ADL self-management and HRQOL among RTAs injured patients previously in Saudi Arabia. Therefore, this research would add to the existing body of knowledge in the field by patient activation for ADL self-management and HRQOL and tries to introduce an intervention module to improve HRQOL through optimizing ADL self-management of RTAs injured patients. This research also, may provide beneficial values to health system by improving quality of care of RTAs injured patients, increasing the efficiency of health services through an ADL self-management module that encourage patients' involvement in recovery and rehabilitation process and empower them to control over their health problems. Similarly, it may also shorten recovery and rehabilitation period, hence, reduce hospital stay which as a result could lead to lessen the financial burden.

8. ETHICAL APPROVAL

In order to conduct this study an ethical approval has been obtained from JKEUPM ethical committee with reference number FPSK (EXP16) P170. In additional to that, Ministry of Health in Saudi Arabia ethical approval has been obtained as well because the study is planned to be conducted in Saudi MOH hospitals,

9. ACKNOWLEDGEMENT

10. CONFLICT OF INTEREST

The authors have no conflict of interest for declaration.

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